REMARKS

Claims 72-91 are pending. Claims 73-79 and 81-89 have been withdrawn from consideration and are now canceled. Claims 72 and 80 have been amended. New claims 92-105 have been added. Support for the amendments can be found, for example, at page 14, lines 35-36 and page 16, line 22 to page 18, line 18. Thus, no new matter has been added and entry of the amendment is respectfully requested. Careful consideration has been given to the grounds for rejection, and the following amendment and discussion are offered in response. Reconsideration is respectfully requested.

The Specification

The claim for priority recited in the first paragraph of page 1 of the specification has been amended to update the priority status of the present application. Specifically, the status of the parent application of the present case was updated to recite the patent number of that issued case.

The Office objected to the brief description of Figure 9 because the figure allegedly did not appear to show BPC-1 mRNA expression in "a bladder carcinoma" cell line. Also, lane 15 of this figure was described as indicating expression, but lane 15 in the figure appeared to the Office as being clear.

In response, it is noted that the numbers indicating the lane run on the gel depicted in Figure 9 appear to be shifted to the right, especially lanes 10-15. This conclusion is supported by the text of the specification in Example 5, which discusses Figure 9. One page 41, lines 10-13, the specification indicates that, "Among the bladder cancer cell lines tested, one (5637) showed detectable BPC-1 expression (FIG. 9)." Examining the bladder portion of the gel depicted in the figure, it clearly shows that one lane indicates the expression of detected material. Applicants submit that this lane is actually lane 15 and the lane description numbers have been shifted to the left. This explanation clarifies the apparent discrepancy noted by the Office. Upon request, Applicants will submit a corrected figure that more accurately displays the lane numbers which correspond to the rows of the gel.

The Office further objected to the specification at page 37, line 30 and page 42 for an allegedly improper disclosure of nucleic acid sequences. In reviewing the present application, an number of other errors regarding the sequence listing were discovered. Applicants have amended the specification at the indicated points to recite sequence identification numbers for the sequences provided at the cited pages. A substitute sequence listing is provided with the present response. The content of the paper and computer read copies of the sequence listing are the same and no new matter has been introduced by way of these amendments or by the submission of the substitute sequence listing.

The Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 72, 80 and 90-91 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to claim the subject matter Applicants regard as the invention with particularity and distinctly. Specifically, the Office has alleged that the term "modulating" is unclear. The Office further alleged that it was unclear as to what was meant by an "altering" composition. Also, with respect to claim 80, the Office alleged that the term "treating" was not clear because a treatment effect was not articulated.

Applicants have amended the pending claim solely to clarify the subject matter regarded as the invention. For example, claim 72 now recites a method of inhibiting 19P1E8 activity by administering a composition capable of inhibiting 19P1E8 activity, whereby the composition inhibits 19P1E8 binding or inhibits expression of 19P1E8. From the context of claims 72 and 80, one of ordinary skill in the art would readily be able to determine that the metes and bounds of these claims.

Regarding the phrase "altering composition", claims 72 and 80 have been amended to recite a composition that inhibits 19P1E8 binding or inhibits expression of 19P1E8. It is this inhibition that constitutes the treatment of the patient as recited in claim 80. Inhibition of 19P1E8 activity can be observed and thus serves as an indication of treatment. This revised wording clearly indicates the metes and bounds of the term as intended by Applicants.

The Office has also rejected claims 72, 80, and 90-91 as allegedly being vague and infinite for reciting the term "19P1E8" as the sole means of identifying the expressed gene referred to in

these claims. Applicants respectfully submit that the identity of the claimed subject matter regarding the term 19P1E8 is clear on its face. Nevertheless, to facilitate prosecution of the present case, the claims have been amended to specify a particular sequence identification number that corresponds to the nucleic acid sequence encoding 19P1E8.

Applicants respectfully submit that the amendments and remarks provided above demonstrate that the pending claims are sufficiently clear, definite and particular to satisfy the requirements of 35 U.S.C. § 112, second paragraph. As such, the present rejections should be withdrawn.

The Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 72, 80 and 90-91 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not being supported by an adequate written description of the claimed invention. To satisfy the written description requirement, a patent application must describe the invention in sufficient detail that one of skill in the relevant art could reasonably conclude that the inventor was in possession of the claimed invention at the time the application was filed. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, (Fed. Cir. 1991). Applicants submit that the claimed invention is adequately supported by the present specification.

To clarify the subject matter of the invention, the pending claims have been amended to recite a method of inhibiting 19P1E8 activity by administering an effective amount of a composition capable of inhibiting 19P1E8 activity, whereby the composition inhibits 19P1E8 binding or inhibits expression of 19P1E8.

The specification supports the claimed methods. For example, the specification explains that BPC-1 (19P1E8) is a secreted protein that is normally expressed only expressed in brain tissue but is also highly expressed in certain cancers (specification at page 25, lines 23-32). The specification contemplates a number of therapeutic approaches directed to inhibiting 19P1E8 activity. These approaches include providing antibodies that bind to 19P1E8 and prevent the protein from interacting with other proteins (see *e.g.*, specification at page 26, line 5 to page 29, line 4). The generation of antibodies that bind to 19P1E8 is discussed in Examples 9 and 10. Additionally, the specification contemplates inhibiting the transcription of the 19P1E8 gene and

translation of the transcription production (see *e.g.*, specification at page 29, line 6 to page 30, line 24).

Applicants submit that the specification, taken as a whole, particularly in view of the passages cited above, would lead one of skill in the relevant art to reasonably conclude that the inventors were in possession of the claimed invention at the time the application was filed. Accordingly, it is believed this basis for rejection may be withdrawn.

Claims 72, 80 and 90-91 also stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not being supported by an enabling disclosure. "To be enabling, the specification of a patent must teach those skilled in the art to make and use the full scope of the claimed invention without 'undue experimentation' ... Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples." *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993).

The pending claims recite methods for inhibiting 19P1E8 activity. As discussed above, the present specification provides a number of tools with which a skilled artisan can readily inhibit 19P1E8 activity. These tools include antibodies that bind to 19P1E8 as well as compositions that inhibit 19P1E8 transcription and translation. One of ordinary skill in the art would not need to engage in undue experimentation to practice the claimed invention in light of these teachings.

Because the skilled artisan could practice the claimed invention without undue experimentation, the pending claims are enabled and thus the present rejection should be withdrawn.

The Rejection Under 35 U.S.C. § 102

Claims 72, 80 and 90 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Coffey et al. (U.S. Patent No. 6,030,793). To be anticipatory prior art under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). Applicants submit that the cited art fails to teach each and every limitation of the claimed invention.

The Coffey reference discloses a number of nuclear matrix proteins, including one designated as "BPC-1", which is defined as benign hyperplasia and cancerous prostate tissue (BPC).

No sequence information is provided in the cited reference. A molecular weight of 42,500 is shown for BPC-1 in Table 1 at column 25, line 9 of the cited reference.

In contrast to the Coffey protein, the claimed protein Brain/Prostate cancer CUB protein (BPC), when recombinantly expressed in 293T cells and labeled with a radioactive amino acid, was shown to have a molecular weight of significantly less than 32,000. This molecular weight is far less than the value attributed to the BPC-1 protein disclosed in the Coffey reference. Example 6 discusses the recombinant expression of the protein and Figure 10 shows an autoradiograph of the immunoprecipitated radio-labeled protein.

Given the dramatic differences between these two proteins, Applicants submit that the protein discussed in the Coffey reference is different from the claimed protein. As such, the Coffey reference does not anticipate the pending claims.

CONCLUSION

Applicants have endeavored to address all of the issues raised by the Patent Office in the outstanding Office Action. As such, Applicants respectfully request that the various rejections and objections noted above be withdrawn and the present claims be passed to allowance. If any questions remain, the Examiner is invited to discuss these matters with the undersigned, who may be reached at the indicated telephone number.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 511582001810.

Respectfully submitted,

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